

License no. 512123-102655296

OFFICIAL DECISION**Operating license for medicinal products****Circumstances**

1. Application dated 8 June 2021, number 102655296
2. Applicant: BACHEM AG
3. Reason for the application:
Change in the scope of the license: Additional active ingredient Aprotinin Acetate
4. Number of previous license: 512123-102638393

Legal bases

- Therapeutic Products Act (TPA; SR 812.21)
- Medicinal Products Licensing Ordinance (MPLO; SR 812.212.1)
- Therapeutic Products Ordinance (TPO; SR 812.212.21)
- Ordinance on Fees Levied by the Swiss Agency for Therapeutic Products (FeeO-Swissmedic; SR 812.214.5)

Swissmedic has decided the following:

1. Holder of the operating license
BACHEM AG
Hauptstrasse 144
4416 Bubendorf
2. The license is numbered 512123-102655296.
3. The license is granted for the following activities:
 - Import of medicinal products
 - Manufacture of medicinal products
 - Wholesale trading in medicinal products
 - Trading abroad in medicinal products
4. Number of operating sites: 1
5. The circumstances described in the annexes apply.
6. The license is valid for an unlimited period from 18 June 2021.
7. Fee: CHF 700.00
8. This license replaces the license referred to in the "Circumstances" section as of the date specified in point 6 above.

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Bern, 18 June 2021

Swissmedic, Swiss Agency for Therapeutic Products

[signature]

Andrea Boschung
Central Dispatch

Your contact:

Department of Inspectorates and Licenses
Secretariat tel. no.: +41 58 462 04 55

Information on the right of appeal:

An appeal against this decision may be filed within 30 days of delivery with the Federal Administrative Court (address: Bundesverwaltungsgericht, Postfach, 9023 St. Gallen) (Art. 31 and 33e of the Federal Act of 17 June 2005 on the Federal Administrative Court; SR 173.32). The appeal document should include a request for remedy, the reasons for the remedy being sought with material cited in evidence and the signature of the appellant or the appellant's representative; the disputed decision and material cited in evidence should be enclosed (Art. 52 of the Federal Act of 20 December 1968 on Administrative Procedure; SR 172.021).

Copies for information:

- Regional Medicines Inspectorate of North-Western Switzerland (RMI)
- Cantonal Pharmacist, Basel-Landschaft

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Annex 1

Operating site 1001480

BACHEM AG
Hauptstrasse 144
4416 Bubendorf

Qualified Person(s)

QP 1
van Bebber, Jan
Chemist, Dr. rer. nat.

QP 2
Morales Rodriguez Peterli, Nubia Stella
Pharmacist, Dr. rer. nat.

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Approved activities / conditions / restrictions

No.	Designation	Scope*	QP
S.2	IMPORT OF MEDICINAL PRODUCTS (EXCLUDING LABILE BLOOD PRODUCTS)		
S.2.1	Import of non-ready-to-use medicinal products		
S.2.1.1	Medicinal products (excluding immunological medicinal products and blood products)	-	2
S.2.1.2	Immunological medicinal products	-	2
3	MANUFACTURE OF ACTIVE PHARMACEUTICAL INGREDIENTS		
3.1	Manufacture of active ingredients by chemical synthesis		
3.1.1	Manufacture of active ingredient intermediates	-	1
3.1.2	Manufacture of crude active pharmaceutical ingredients	-	1
3.1.3	Salt formation / purification steps: HPLC, ultrafiltration, crystallization	-	1
3.5	Final production steps		
3.5.1	Physical processing steps: Freeze-drying, drying, milling	-	1
3.5.2	Primary packing	-	1
3.5.3	Secondary packing	-	1
3.6	Quality control of medicinal products		
3.6.1	Chemical / physical analytics	-	1
3.6.2	Microbiological analytics, excluding sterility testing	-	1
3.8	List of active pharmaceutical ingredients: Antazoline Hydrochloride, Antazoline Phosphate, Antazoline Sulfate, Aprotinin Acetate, Atosiban Acetate, Bivalirudin, Buserelin, Calcitonin (salmon), Deslorelin High Acetate, Glucagon, Gonadorelin Acetate, Goserelin Acetate, Histrelin Acetate, Icatibant Acetate, Leuprolide Acetate, Nitisinone, Octreotide Acetate, Somatostatin, Tetracosactide, Triptorelin Acetate, Triptorelin Pamoate		1
S.4	WHOLESALE TRADING IN MEDICINAL PRODUCTS (EXCLUDING LABILE BLOOD PRODUCTS)		
S.4.1	Wholesale trading in non-ready-to-use medicinal products		
S.4.1.1	Medicinal products (excluding immunological medicinal products and blood products)	-	2
S.4.1.2	Immunological medicinal products	-	2
S.6	TRADING ABROAD IN MEDICINAL PRODUCTS (EXCLUDING LABILE BLOOD PRODUCTS)		
S.6.1	Trading abroad in non-ready-to-use medicinal products, without storage in Switzerland		
S.6.1.1	Medicinal products (excluding immunological medicinal products and blood products)	-	2
S.6.1.2	Immunological medicinal products	-	2

*see last page

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Scope of approved activities (for all annexes)

- H/V Medicinal products for use in human medicine (human medicinal products) and veterinary medicine (veterinary medicinal products), excluding medicinal products for clinical trials
- V Medicinal products exclusively for use in veterinary medicine (veterinary medicinal products)
- I Human medicinal products for clinical trials
- Not specified

CONFIRMATION

This is to confirm that the English translation of the following document:

- **Swissmedic**
Verfügung Betriebsbewilligung Arzneimittel
Bewilligung Nr. 512123-102655296
Bachem AG
Bern, 18.06.2021

is to the best of my knowledge and ability, a faithful and accurate rendering of the original German text. The translation corresponds in all respects to the wording of the original.

bmp translations ag

John Purnell

Basel, June 29, 2021

LEGALISATION

We hereby certify that the signature of

BMP Translations AG

of Basel (Switzerland), which is known to us, is genuine, and that the person/s, who signed on its behalf, viz.

Purnell John translator

who is/are personally known to us, is/are authorized to sign jointly/individually.

No. **205052**

tax: **CHF 15.00**

Basel, **29.06.2021**

**LEGALISATION OFFICE OF THE
CANTON OF BASEL-CITY**

Saulo Fischer




The certification refers exclusively to the signature and not the content or the authenticity of the signed document.